Atty. Dkt. No. 032026-0769



Applicant: Guilherme L. INDIG

Title: USE OF CRYSTAL VIOLET AS

**PHOTOCHEMOTHERAPEUTIC** 

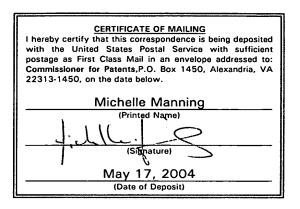
AGENT

Appl. No.: 10/751,302

Filing Date: 01/02/2004

Examiner: Unknown

Art Unit: 1615



## INFORMATION DISCLOSURE STATEMENT **UNDER 37 CFR §1.56**

Mail Stop MISSING PARTS Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO-1449 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56, including documents cited by or submitted to the U.S. PTO in parent application Serial No. 09/753,472, filed 01/02/2001. As provided in 37 C.F.R. § 1.98(d), copies of the documents cited by or submitted to the U.S. PTO are not being provided since they were previously submitted to the U.S. PTO in the above-identified parent application. A copy of each remaining document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a prima facie art reference against the claims of the present application.

## **TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

## RELEVANCE OF EACH DOCUMENT

An English translation of the foreign-language document is not readily available. However, the absence of such translation does not relieve the PTO from its duty to consider the submitted foreign language document (37 CFR §1.98 and MPEP §609).

Applicant respectfully requests that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO-1449 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-2350. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-2350.

Respectfully submitted,

Michelle Manning

Attorney for Applicant

Registration No. 50,592

Date May 17, 2004

FOLEY & LARDNER LLP Customer Number: 23524 Telephone: (608) 258-4305

Facsimile: (608) 2

(608) 258-4258

communication to applicant.

Page 2 of 6

			<u>Page 2 of 6</u>
Form PTO-1449	U.S. DEPARTMENT OF COMMERCE	ATTY. DOCKET NO.	SERIAL NO.
(MODIFIED)	PATENT AND TRADEMARK OFFICE	032026-0769	10/751,302
		APPLICANT	
INFORMA	TION DISCLOSURE CITATION	Guilherme I	I. INDIG
		FILING DATE	GROUP ART UNIT
(Use several sheets if necessary)		01/02/2004	1615
	OTHER DOCUMENTS (Including A	Author, Title, Date, Pertinent Pages,	Etc.)
	Bartlett J. A. et al., "Effect of Self-associal Triarylmethanes. Implications of Noncov Mechanisms Type I and Type II," Photocial Photobiology.	alent Interactions on the Competition b	etween Photosensitization
	Bartlett, J. A. et al., "Spectroscopic and p bovine serum albumin," Dyes and Pigmen	hotochemical properties of Malachite (nts, Vol. 43, pp. 219-226, 1999; Elsevi	Green noncovalently bound to er Science Ltd.
	Chance, B., "Fluorescent probe environm mitochondrial membranes," Proc. Natl. A		
	Chen, L. B., "Mitochondrial membrane po Annual Reviews Inc.	otential in living cells," Ann. Rev. Cell B	iol., Vol. 4, pp. 155-181, 1988;
	Davis, S. et al., "Mitochondrial and plasm rhodamine 123 by human breast adenoca 13850, 1985; The American Society of Bi	arcinoma-derived MCF-7 cells," J. Biol.	accumulation and retention of <i>Chem.</i> , Vol. 260, pp. 13844-
·	Denk, W. et al., "2-photon laser scanning	fluorescence spectroscopy," Science,	Vol. 248, pp. 73-76, 1990.
	Docampo, R. et al., "Light enhanced free violet)," Science, Vol. 220, pp. 1292-1294		ion of gentian violet (crystal
	Docampo, R. et al., "Prevention of Chaga toxicity and mode of action of gentian viol Press, Inc.		
	Docampo, R. et al., "Enhancement of the by ascorbate," Molec. Biochem. Parasitol	cytotoxicity of crystal violet against <i>Tr</i> <sub>3</sub> ., Vol. 27, pp. 241-248, 1988; Elsevier	ypanospoma cruzi in the blood Science Publishers B.V.
	Duxbury, D. F., "The photochemistry and Chem. Rev., Vol. 93, pp. 381-433.	photophysics of triphenylmethane dye	s in solid and liquid media,"
	Dyer, H. M., An Index of Tumor Chemothe	erapy, <i>NIH</i> , Aug. 13, 1951, pp. 10-12,	123 and 124.
	Fiedorowicz, M. et al., "Efficient Photodyn Lines K-562 and TF-1," Photochemistry a for Photobiology.		
	Fiedorowicz, M. et al., "The Photodynamic Leukemic Cells," <i>Photochem. Photobiol.</i> , Photobiology.	c Effect of Victoria Blue BO on Periphe Vol. 65, No. 5, pp. 855-861, 1997; Am	eral Blood Mononuclear and erican Society for
	Fischer, V. et al., "Spectroscopic studies electron spin resonance investigations of Vol. 7, pp. 11-119, 1984; Elsevier Science	the photoreduction of gentian (crystal)	V. Spin trapping and direct violet," Photochem. Photobiol.,
	Foote, C. S., "Mechanism of photosensitized	zed oxidation," Science, Vol. 162, No.	3857, pp. 963-970, 1968.

Page 3 of 6

F DTO 4440	LLC DEDARTMENT OF COMMERCE	ATTY, DOCKET NO.	SERIAL NO.	
Form PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	032026-0769	10/751,302	
(MODIFIED)	PATERI AND HADEMAIN OFFICE	APPLICANT	10,731,302	
INFORMAT	TION DISCLOSURE CITATION	I · · · · = ·	E L. INDIG	
(Use several sheets if necessary)		FILING DATE	GROUP ART UNIT	
		01/02/2004	1615	
<del>`</del>	OTHER DOCUMENTS (Including A	uthor. Title. Date. Pertinent Pag	es, Etc.)	
	Foote, C. S., "Definition of type I and type	_		
	p. 659, 1991; Pergamon Press plc, printe	d in Great Britain.		
	Gadelha, F. R. et al., "The mitochondrion Parasitol., Vol. 34, pp. 117-126, 1989; Els			
	Gaffney D. K. et al., "Merocyanine 540-se effects on plasma membrane integrity an International Society for Experimental He	d mitochondrial respiration," Exp. F		
	Hamal, S. et al., "Actinometric determinal 87, pp. 83-89, 1983; American Chemical		um yields," <i>J. Phys. Chem.</i> , Vol.	
	Hatchard, D. G., "A new sensitive chemical actinometer. II. Potassium ferrioxalate as a standard chemical actinometer," <i>Proc. R. Soc. London</i> , Ser. A, Vol. 235, pp. 518-536, 1956.			
	Indig, G. L., "Photochemistry of triarylmet Tumor Treatment and Detection: Mechan 228-237, 1996; Society of Photo-Optical	nisms and Techniques in Photodyn		
	Indig, G. L., "Mechanism of Dye Bleachin Albumin," Chemistry Letters, pp. 243-244			
	Indig, G. L., "Mechanisms of action of cat Pure & Applied Chem., Vol. 3, pp. 9-19, 1	ionic dyes in photodynamic therapy 1999.	of tumors," Recent Res. Devel.	
-	Indig, G. L., "Effect of Molecular Structure for Photochemical Purging of Autologous 89, No. 1, pp. 88-99, 2000; Wiley-Liss, In	Bone Marrow Grafts from Residua	l Tumor Cells," J. Pharm. Sci., Vol	
	Indig, G., et al., "Effect of Molecular Structure Normal Cells," Abstract, 30 <sup>th</sup> Annual Mee July 13-17, 2002; Allen Press, Inc. 2001.	ture on the Phototoxicity of TriaryInting of the American Society for Ph	nethane Dyes Towards Tumor and otobiology, Quebec City, Canada,	
	Iscove, N. N. et al., "Erythroid colony forn requirement for erythropoietin by gel filtra <i>Physiol.</i> , Vol. 83, pp. 309-320, 1974.			
	Jockusch, S. et al., "Radical addition rate produced by photolysis of photoinitiators, Chemical Society.			
·	Kandela, I. K. et al., "Effect of Molecular S Towards Tumor Cells," <i>J. Pharm. Sci.</i> , Vo 314, 2002; The Royal Society of Chemist	ol. 89, No. 1, January 2000, and <i>Ph</i>		
	Kasha, M. et al., "The exciton model in molecular spectroscopy," <i>Pure Appl. Chem.</i> , Vol. 11, pp. 371-392, 1965.			

Page 4 of 6 ATTY. DOCKET NO. Form PTO-1449 U.S. DEPARTMENT OF COMMERCE SERIAL NO. (MODIFIED) PATENT AND TRADEMARK OFFICE 032026-0769 10/751,302 APPLICANT INFORMATION DISCLOSURE CITATION Guilherme L. INDIG FILING DATE **GROUP ART UNIT** (Use several sheets if necessary) 01/02/2004 1615 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Kawakami, M. et al., "Synthesis and evaluation of novel rhodacyanine dyes that exhibit antitumor activity," J. Med. Chem., Vol. 40, pp. 3151-3160, 1997; American Chemical Society. Kowaltowski, A. J. et al., "Mitochondrial effects of triarylmethane dyes," J. Bioenerg. Biomembr., Vol. 31, pp. 579-588, 1999; Plenum Publishing Corporation. Koya, K. et al., "MKT-077, a novel rhodacyanine dye in clinical trials, exhibits anticarcinoma activity in preclinical studies based on selective mitochondrial accumulation," Cancer Res., Vol. 56, pp. 538-543, 1996. Kraljic, I. et al., "A new method for the detection of singlet oxygen in aqueous solution," *Photochem. Photobiol.*, Vol. 28, pp. 577-581, 1978; Pergamon Press Ltd. Leo, A. et al., "Partition coefficients and their uses," Chem. Rev., Vol. 71, No. 6, pp. 525-616, 1971. Lewis, M. R. et al., "The Tumor-inhibitory Activity of Diaryl- and Triarylmethane Dyes," Cancer Research, Vol. 13, pp. 130-136, 1953. Liao, Y. et al., "Alcohol effect on equilibrium constants and dissociation dynamics of xanthone-cyclodextrin complexes," J. Phys. Chem., Vol. 11, pp. 734-743, 1996; American Chemical Society. Lueck, H. B. et al., "Aggregation of triphenylmethane dyes in aqueous solution: dimerization and trimerization of crystal violet and ethyl violet," Spectrochim Acta, Vol. 48A, pp. 819-828, 1992; Pergamon Press Ltd. Modica-Napolitano, J. S., "Photoactivation Enhances the Mitochondrial Toxicity of the Cationic Rhodacyanine MKT-077," Cancer Res., Vol. 58, pp. 71-75, 1998. Moraes-Souza, H. et al., "Strategies for prevention of transfusion-associated Chagas' disease," Transf. Med. Rev., Vol. X, No. 3, pp. 161-170, 1996; W. B. Saunders Company. Moreno, S. N. J. et al., "Crystal Violet as an Uncoupler of Oxidative Phosphorylation in Rat Liver Mitochondria," J. Biol. Chem., Vol. 263, pp. 12493-12499, 1988; The American Society for Biochemistry and Molecular Biology, Inc. Morgan, A. R. et al., "Synthesis and in vivo Activity of Some Porphyrindione Derivatives with Potential in Photodynamic Therapy," Journal of Photochemistry and Photobiology, B: Biology, Vol. 6, pp. 133-141, 1990; Elsevier Sequoia/Printed in The Netherlands. Morgan, A. R. et al., "Diels-Alder Adducts of Vinyl Porphyrins: Synthesis and in Vivo Photodynamic Effect against a Rat Bladder Tumor," J. Med. Chem., Vol. 33, pp. 1258-1262, 1990; American Chemical Society.

Morgan, A. R. et al., "Tin Etiopurpurin Dichloride-Sensitized Lipid Photooxidation of Erythrocyte Membranes," *Photochemistry and Photobiology*, Vol. 52, No. 5, pp. 987-991, 1990; Pergamon Press, Great Britain.

Page 5 of 6 Form PTO-1449 U.S. DEPARTMENT OF COMMERCE ATTY, DOCKET NO. SERIAL NO. (MODIFIED) PATENT AND TRADEMARK OFFICE 032026-0769 10/751,302 **APPLICANT** INFORMATION DISCLOSURE CITATION Guilherme L. INDIG **FILING DATE GROUP ART UNIT** (Use several sheets if necessary) 01/02/2004 1615 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Morgan, J. et al., "GRP78 induction by calcium ionophore potentiates PDT using the mitochondrial targeting dye Victoria Blue BO," Photochem. Photobiol., Vol. 67, No. 1, pp. 155-164, 1998; American Society for Photobiology. Nussenzweig, V. et al., "Action of certain dyes on T. cruzi in vitro. The use of gentian violet to prevent the transmission of Chagas," Hospital (Rio J.), Vol. 44, No. 6, pp. 731-744, 1953. Oseroff, A. R., "Cationic Sensitizers, Combination Therapies, and New Methodologies," Photodynamic therapy: Basic principles and clinical applications, pp. 79-96, 1992; Dekker, New York. Patel, J. et al., "Design of Novel Analogs of Victoria Blue BO (VBBO) for Photodynamic Therapy," Abstracts of Papers of the American Chemical Society, Vol. 203, April 5-10, 1992, San Francisco, California. Ramirez, L. E. et al., "Prevention of transfusion-associated Chagas' disease by sterilization of Trypanosoma cruzi-infected blood with gentian violet, ascorbic acid, and light," Transfusion, Vol. 35, No. 3, pp. 226-230, 1995. Reszka, K. et al., "Photosensitization by the trypanocidal agent crystal violet. Type I versus type II reactions," Chem. Biol. Interactions, Vol. 58, pp. 161-172, 1986; Elsevier Scientific Publishers Ireland Ltd. Riley, J. F., M.D., "Retardation of Growth of a Transplantable Carcinoma in Mice Fed Basic Metachromatic Dyes," Cancer Research, Vol. 8, pp. 183-188, 1948. See-Lasley, K. et al., Manual of Oncology Therapeutics, pp. 88 and 104, 1981; The C. V. Mosby Company. Sieber, F. et al., "Selective killing of leukemic cells by merocyanine 540-mediated photosensitization," Proc. Natl. Acad. Sci. USA, Vol. 81, pp. 7584-7587, 1984. Sundstrom, V. et al., "Picosecond kinetics of radiationless relaxations of triphenylmethane dyes. Evidence for a rapid excited-state equilibrium between states of differing geometry," Chem. Phys., Vol. 73, pp. 439-458, 1982; North-Holland Publishing Company. Traul, D. L. et al., "Potentiation of Merocyanine 540-Mediated Photodynamic Therapy by Salicylate and Related Drugs," Photochemistry and Photobiology, Vol. 62, No. 4, pp. 790-799, 1995; American Society for Photobiology. Viola, A. et al., "Electron paramagnetic resonance evidence of the generation of superoxide and hydroxyl radicals by irradiation of a new photodynamic therapy photosensitizer, Victoria Blue BO," J. Photochem. Photobiol. B: Biol, Vol. 32, pp. 49-58, 1996; Elsevier Science S.A. Vogel, M., "Efficient intramolecular fluorescence quenching in triphenylmethane dyes involving excited states with charge separation and twisted conformations," Ber Bunsen-Ges. Phys. Chem., Vol. 89, pp. 962-968, 1985; VCH Verlagsgesellschaft mbH, D-6940 Weinheim. Wadwa, K. et al, "Cationic Triarylmethane Photosensitizers for Selective Photochemotherapy: Victoria Blue-BO, Victoria Blue-R and Malachite Green," Advances in Photochemotherapy, Vol. 997, pp. 154-161, 1988. Yamazaki, T. et al., "Role of Cytoprotective Mechanisms in the Photochemical Purging of Autologous Bone Marrow Grafts," Experimental Hematology, Vol. 25, pp. 629-637, 1997; International Society for Experimental

Hematology.

Page 6 of 6 Form PTO-1449 U.S. DEPARTMENT OF COMMERCE ATTY. DOCKET NO. SERIAL NO. (MODIFIED) PATENT AND TRADEMARK OFFICE 032026-0769 10/751,302 APPLICANT **INFORMATION DISCLOSURE CITATION** Guilherme L. INDIG **FILING DATE GROUP ART UNIT** 01/02/2004 (Use several sheets if necessary) 1615 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Yamazaki, T. et al., "The Alkyl-lysophospholipid, ET-18-OCH<sub>3</sub> Synergistically Enhances the Merocyanine 540-Mediated Photoinactivation of Leukemia Cells: Implications for the Extracorporeal Purging of Autologous Hematopoietic Stem Cells," *Bone Marrow Transplantation*, Vol. 19, pp. 113-119, 1997; Stockton Press.